

PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	09/863,006
Filing Date	May 22, 2001
First Named Inventor	Gene W. Zdenek
Art Unit	3738
Examiner Name	W. Matthews
Attorney Docket Number	PRES06-00208

Sheet	1	of	12
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**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
[Signature]	AA	US- 4,439,198	03/27/1984	Brightman, II et al	
	AB	US- 4,521,210	06/04/1985	Wong	
	AC	US- 4,549,529	10/29/1985	White	
	AD	US- 4,863,457	09/05/1989	Lee	
	AE	US- 5,465,737	11/14/1995	Schachar	
	AF	US- 5,489,299	02/06/1996	Schachar	
	AG	US- 5,503,165	04/02/1996	Schachar	
	AH	US- 5,529,076	06/25/1996	Schachar	
	AI	US- 5,707,643	01/13/1998	Ogura et al.	
	AJ	US- 5,722,952	03/03/1998	Schachar	
	AK	US- 5,731,909	03/24/1998	Schachar	
	AL	US- 5,774,274	06/30/1998	Schachar	
	AM	US- 5,824,086	10/20/1998	Silverstrini	
	AN	US- Re 35,974	12/01/1998	Davenport et al.	
	AO	US- 5,846,256	12/08/1998	Mathis et al	
	AP	US- 5,855,604	01/05/1999	Lee	
	AQ	US- 5,888,243	03/30/1999	Silverstrini	
	AR	US- 5,919,228	07/06/1999	Hennig	
	AS	US- 5,944,752	08/31/1999	Silverstrini	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>4</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
[Signature]	AT	WO 94/18921	09/01/1994			
	AU	WO 00/25703	05/11/2000			
	AV	WO 99/17684	04/15/1999			
	AW	WO 99/17691	04/15/1999			

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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First Named Inventor	Gene W. Zdenek
Art Unit	3738
Examiner Name	W. Matthews
Attorney Docket Number	PRES06-00208

Sheet	2	of	12
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## U. S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

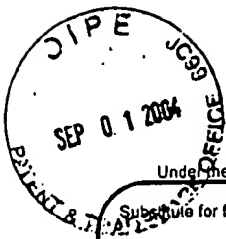
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**NON PATENT LITERATURE DOCUMENTS**

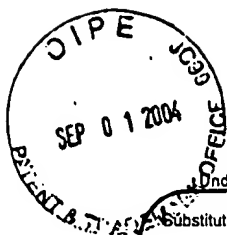
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
WZ	CA	Schachar, "Cause and Treatment of Presbyopia With a Method for Increasing the Amplitude of Accommodation," Ann Ophthalmol, 24: 445-452 (1992).	
	CB	Schachar, et al., "Mathematic Proof of Schachar's Hypothesis of Accommodation," Ann Ophthalmol, 25: 5-9 (1993).	
	CC	Schachar, et al., "Experimental Support for Schachar's Hypothesis of Accommodation," Ann Ophthalmol 25: 404-409 (1993).	
	CD	Schachar, et al., "A Physical Model Demonstrating Schachar's Hypothesis of Accommodation," Ann Ophthalmol 26:4-9 (1994).	
	CE	Schachar, "Zonular Function: A New Hypothesis with Clinical Implications," Ann Ophthalmol 26: 36-38 (1994).	
	CF	Schachar, et al., "The Effect of Gravity on the Amplitude of Accommodation," Ann Ophthalmol 26: 65-70 (1994).	
	CG	Schachar, et al., "The Mechanism of Accommodation and Presbyopia in the Primate," Ann Ophthalmol 27:58-67 (1995).	
	CH	Schachar, et al., "The Mechanism of Ciliary Muscle Function," Ann Ophthalmol 27:126-132 (1995).	
	CI	Schachar, "Histology of the Ciliary Muscle-Zonular Connections," Ann Ophthalmol 28:70-79 (1996).	
	CJ	Schachar, et al., "Equatorial Diameter During Accommodation," American Physiological Society R670-R676 (1996).	

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Examiner Name	W. Matthews
Attorney Docket Number	PRES06-00208

Sheet	4	of	12
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**NON PATENT LITERATURE DOCUMENTS**

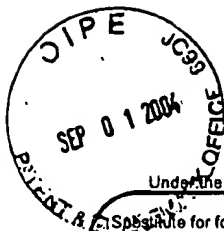
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
WZ	DA	Yee, et al., "Scleral Expansion: New Surgical Technique to Correct Presbyopia," Investigative Ophthalmology & Visual Science, Vol. 30(4), 5 (1997).	
	DB	Glasser, et al., "Presbyopia and the Optical Changes in the Human Crystalline Lens with Age," Vision Res., 38:209-229 (1998).	
	DC	Schachar, "Pathophysiology of Accommodation and Presbyopia," J. Florida M.A. 81:268-271 (1994).	
	DD	Schachar, et al., "A Revolutionary Variable Focus Lens," Annals of Ophthalmology, 28:11-18 (1996).	
	DE	Adler-Grinberg, "Questioning Our Classical Understanding of Accommodation and Presbyopia," Am. J. Optometry & Physiological Optics, 63(7) 571-580 (1986).	
	DF	Omi, et al., "Modified Schochet Implant for Refractory Glaucoma," Ophthalmology 98:211-214 (1991).	
	DG	Arons, "LASIK and PRK clinical results are hot topics at the RSIG and ISRS meetings," Ocular Surgery News, <a href="http://www.slackline.com/eye/osn/19901a/lasik/asp">http://www.slackline.com/eye/osn/19901a/lasik/asp</a> , January 1, 1999.	
	DH	Atchison, "Accommodation and Presbyopia," Ophthal Physiol. Opt. 15(4):255-272 (1995).	
	DI	Bernatchez, et al., "Biocompatibility of a new semisolid bioerodable poly(orth ester) intended to the ocular delivery of 5-fluorouracil," J. Biomedical Materials Research, 28:1037-1046 (1994).	
✓	DJ	Billson, et al., "Resiting Molteno Implant Tubes," Ophthalmic Surgery and Lasers, 27:801-803 (1996).	

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Sheet	5	of	12	Attorney Docket Number	PRES06-00208

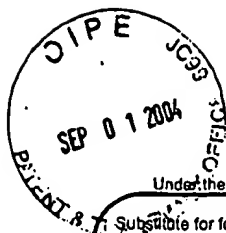
NON PATENT LITERATURE DOCUMENTS			
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22	EA	Brockhurst, "Dystrophic Calcification of Silicone Scleral Buckling Implant Materials," Am. J. Ophthalmol, 115:524-529 (1993).	
	EB	Brouillette, et al., "Long-term results of modified trabeculectomy with Supramid implant for neovascular glaucoma," Can. J. Ophthalmol, 22(5):254-256 (1987).	
	EC	Cameron, et al., "Clinico-histopathologic Correlation of a Successful Glaucoma Pump-shunt Implant," Ophthalmology, 95:1189-1194 (1988).	
	ED	Campbell, et al., "Fluctuations of Accommodation Under Steady Viewing Conditions," J. Physiol., 145:579-594 (1959).	
	EE	Coleman, et al., "Initial Clinical Experience with the Ahmed Glaucoma Implant," Am. J. Ophth. 120:23-31 (1995).	
	EF	Coleman, et al., "Clinical Experience with the Ahmed Glaucoma Valve Implant in Eyes with prior or Current Penetrating Keratoplasties," Am. J. Ophth., 123:54-61 (1997).	
	EG	Colosi, et al., "Intrusion of Scleral Implant Associated with Conjunctival Epithelial Ingrowth," Am. J. Ophthalmol, 83:504-507 (1997).	
	EH	Coltair, et al., "Scleral Pocket Incision Applied to Insertion of the Nut and Bolt Keratoprosthesis," J. Cataract Refract. Surg., 16:649-651 (1990).	
	EI	Crucea, et al., "Artificial Drainage Devices in Glaucoma" Optalmologia, 47(2):5-10, Abstract only.	
✓	EJ	Daniele, et al., "Gelatin as an Absorbable Implant in Scleral Buckling Procedures," Arch Ophthal, 80:115-119 (1968).	

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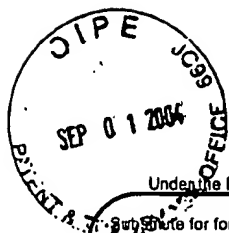
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WZ	FA	Elander, "Scleral Expansion Surgery does not restore accommodatino in human presbyopia," J. Refract. Surg., 15(5):604 (1999).	
	FB	Ellis, "Surgical Conquest of presbyopia; Are There Implications for Cataract and Glaucoma," Refractive Surgery, 38-44 (1999).	
	FC	El-Sayyad, "The Use of Releasable Sutures in Molteno Glaucoma Implants to Reduce Postoperative Hypotony," Ophthalmic Surgery, 22:82-84 (1991).	
	FD	Girard, et al., "Scleral fixation of a subluxated posterior chamber intraocular lens," J. Cataract Refract. Surg., 14:326-327 (1988).	
	FE	Hashizoe, et al., "Implantable biodegradable polymeric device in the treatment of experimental proliferative vitreoretinopathy," Curr. Eye Res., 14(6):473-477 (1995).	
	FF	Hashizoe, et al., "Scleral plug of biodegradable polymers for controlled drug release in the vitreous," Arch. Ophthalmol., 112(10):1380-1384 (1994).	
	FG	Hashizoe, et al., "Biodetgradable polymeric devices for sustained intravitreal release of glanciclovir in rabbits," Current Eye Research, 112(10): 633-339 (1997).	
	FH	Hasty, et al., "Primate Trabeculectomies with 5-fluorouracil Collagen Implants," Am. J. Ophthalmol, 109:721-725 (1990).	
	FI	Hilton, et al., "The Removal of Scleral Buckles," Arch Ophthalmol, 96:2061-2063 (1978).	
✓	FJ	Ho, et al., "The MAI hydrophilic implant for scleral buckling: a view," Ophthalmic Surg., (6):611-5 (1984).	

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WZ	GA	Jacklin, et al., "Gelatin as an Absorbable Implant in Scleral Buckling Procedure," Arch. Ophthalmol, 79:286-289 (1968).	
	GB	Jacob, et al., "Synthetic scleral reinforcement materials. II Collagen types in the fibrous capsule," J. Biomedical Materials Research, 32:181-186 (1966).	
	GC	Krupin, et al., "Filtering Valve Implant Surgery for Eyes with Neovascular Glaucoma," Am. J. Ophthalmol, 89:338-343 (1980).	
	GD	Krupin, et al., "Long-Term Results of Valve Implants in Filtering Surgery Eyes with Neovascular Glaucoma," Am. J. Ophthalmol, 95:775-782 (1983).	
	GE	Krupin, et al., "A Long Krupin-Denver Valve Implant Attached to a 180 Scleral Explant for Glaucoma Surgery," Ophthalmol, 95:1174-1180 (1988).	
	GF	Kimura, et al., "A new Vitreal Drug Delivery System Using an Implantable Biodegradable Polymeric Device," Investigative Ophthalmol and Visual Science, 35:2815-2819 (1994).	
	GG	King, et al., "Gelatin Implants in Scleral Buckling Procedures," Arch. Ophthalmol., 93:807-811 (1975).	
	GH	Lambert, et al., "Wedge Implant Used as an Explant," Am. J. Ophthalmol., 101:488-489 (1986).	
	GI	Lambert, et al., "A New Alloplastic Material for Ophthalmic Surgery," Ophthalmic Surgery, 9:35-42 (1978).	
✓	GJ	Law, et al., "Retinal Complications after Aqueous Shunt Surgical Procedures for Glaucoma," Arch Ophthalmol, 114:1473-1480 (1996).	

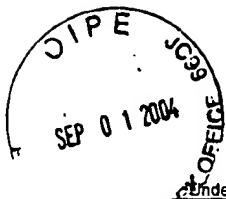
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

8

of

12

**Complete if Known**

Application Number

09/863,006

Filing Date

May 22, 2001

First Named Inventor

Gene W. Zdenek

Art Unit

3738

Examiner Name

W. Matthews

Attorney Docket Number

PRES06-00208

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
2W	HA	Levit, et al., "Use of Ophthalmic Gelfilm in retinal Surgery," Ann. Ophthalmol, 1613-1616 (December 1975).	
	HB	Lipner, "A Closer Look at Scleral Surgery," Eyeworld (September 13, 1999) <a href="http://www.eyeworld.org/sep99/999p34.asp">http://www.eyeworld.org/sep99/999p34.asp</a>	
	HC	Lincoff, et al., "The Changing Character of the Infected Scleral Implant," Arch. Ophthalmol, 84:421 et seq (1970).	
	HD	Liu, et al., "Scleral Buckling with a Soft Xerogel Implant: II Experiments in Vivo," Ophthalmic Surgery, 10:52-56 (1979).	
	HE	Lloyd, et al., "Initial Clinical Experience with Baeveldt Implant in Complicated Glaucomas," Ophthalmology, 101:650-640 (1994).	
	HF	Luttrull, et al., "Pars Plana Implant and Vitrectomy for Treatment of Neovascular Glaucoma," Retina, 15:379-387 (1995).	
	HG	Luttrull, et al., "Initial Experience with Pneumatically Stented baerveldt implant modified for Pars Plana Insertion in Complicated Glaucoma," Ophthalmology, 107:143-149 (2000).	
	HH	Marin, et al., "Long-term Complications of the MAI Hydrogel Intrasccleral Buckling Implant," Arch. Ophthalmol, 110:86-88 (1992).	
	HI	Matthews, et al., "Scleral Expansion Surgery Does Not Restore Accommodation in Human Presbyopia, Ophthalmology, 106:873-877 (1999).	
✓	HJ	Melamed, et al., "Molteno Implant Surgery in Refractory Glaucoma," Survey of Ophthalmology, 34:441-448 (1990).	

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SignatureDate  
Considered

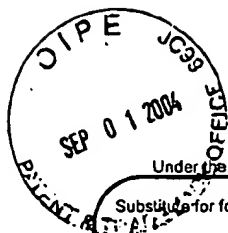
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	09/863,006		
		Filing Date	May 22, 2001		
		First Named Inventor	Gene W. Zdenek		
		Art Unit	3738		
		Examiner Name	W. Matthews		
Sheet	9	of	12	Attorney Docket Number	PRES06-00208

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
WZ	IA	Minckler, et al., Clinical Experience with the Single-plate Molteno Implant in Complicated Glaucomas," Ophthalmology 95:1181-1188 (1988).	
	IB	Miyamoto, et al., "Biodegradable Scleral Implant for Controlled Release of Flucanazole," Current Eye Research, 16:930-935 (1997).	
	IC	Ocular Surgery News, "Presbyopia Reversible in Pilot Studies," July 1, 1999; <a href="http://www.slackinc.com/eve/osn/199907a/presby.asp">http://www.slackinc.com/eve/osn/199907a/presby.asp</a>	
	ID	Peiffer, et al., "Long-term Comparative Study of the Schochet and Joseph Glaucoma Tube Shunts in Monkeys," Ophthalmic Surgery, 21:55-59 (1990).	
	IE	Pruett, "The Fishmouth Phenomenon," Ach. Ophthalmol, 95:1777-181 (1977).	
	IF	Rabowsky, et al., "The Use of Bioerodeable Polymers and Daunorubicin in Glaucoma Filtration Surgery," Ophthalmology, 103:800-807 (1996).	
	IG	Ray, et al., "Gelatin Implants in Scleral Buckling Procedures," Arch Ophthalmol, 93:799-802 (1975).	
	IH	Refojo, "Polymers in Ophthalmic Surgery," J. Biomed. Mater. Res., 5:113-119 (1971).	
	II	Refojo, et al., "Experimental Scleral Buckling with a Soft Xerogel Implant," Ophthalmic Surgery, 9:43-50 (1978).	
✓	IJ	Riggs, et al., "Intraocular Silicone Prostheses in a Dog and a Horse with Corneal Lacerations," J. Am. Vet. Med. Assoc., 196:617-619 (1990).	

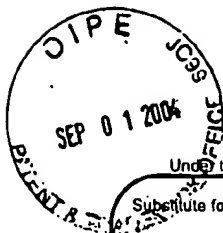
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		Art Unit	3738		
		Examiner Name	W. Matthews		
Sheet	10	of	12	Attorney Docket Number	PRES06-00208

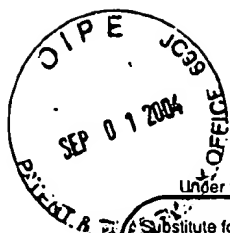
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WZ	JA	Rohr, et al., "Surgical Correction of Presbyopia," J. Osteopathic College of Ophthalmology and Otolaryngology, 12:34-36 (2000).	
	JB	Rubsamen, et al., "Prevention of Experimental Poliferative Vitreoretinopathy with a Biodegradable Intravitreal Implant for the Sustained Release of Fluoroacil," Arch. Ophthalmol. 112:407-413 (1994).	
	JC	Sakamoto, et al., "Silicone Sponge Implant in Combination with Episcleral Implant for Retinal Surgery," Ophthalmic Surgery, 11:712-718 (1980).	
	JD	Sarkies, et al., "Silicone Tube and Gutter in Advanced Glaucoma," Trans. Ophthalmol. Soc. U.K., 144:133-136 (1985).	
	JE	Schepens, et al., "Scleral Implants: An Historic Perspective," Survey of Ophthalmology, 35:447-453 (1991).	
	JF	Sherwood, et al., "Surgery for Refractory Glaucoma," Arch. Ophthalmol, 105:562-569 (1987).	
	JG	Sidoti, et al., "Epithelial Ingrowth and Glaucoma Drainage Implants," Ophthalmol, 101:872-875 (1994).	
	JH	Sidoti, et al., "Aqueous Tube Shunt to a Pre-existing Episcleral Encircling Element in the Treatment of Complicated Glaucomas," Ophthalmol, 101:1036-1043 (1994).	
	JI	Smith, et al., "One-year results of the intrascleral glaucoma implant," J Cataract Refract. Surg., 21:453-456 (1995).	

Examiner Signature	<i>WZ</i>	Date Considered	4/4/05
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Application Number	09/863,006
Filing Date	May 22, 2001
First Named Inventor	Gene W. Zdenek
Art Unit	3738
Examiner Name	W. Matthews
Attorney Docket Number	PRES06-00208

Sheet	11	of	12
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**NON PATENT LITERATURE DOCUMENTS**

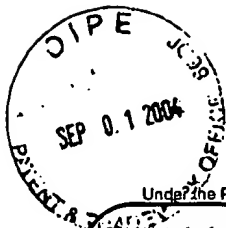
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212	KA	Smith, et al., "Comparison of the Double-Plate Molteno Drainage Implant with the Schochet Procedure," Arch. Ophthalmol, 110:1246-1250 (1992).	
	KB	Speigel, et al., "Anterior Chamber Tube Shunt to an Encircling Band (Schochet procedure) in the Treatment of Refractory Glaucoma," Ophthalmic Surgery, 12:804-807 (1992).	
	KC	Strubble, et al., "In vitro low characteristics of the Amhed and self-constructed anterior chamber shunts," Am. J. Vet. Res., 58:1332-1337 (1997).	
	KD	Sveinsson, et al., "Trabeulectomy and gelatin implants," Acta Ophthalmologica, 70:645-650 (1992).	
	KE	Susanna, "Modifications of the Molteno Implants and implant Procedure," Ophthalmic Surgery, 22:611-613 (1991).	
	KF	Szymanski, "Scleral free auto-implant plug with mitomycin as limitation of trepanosclerectomy flow in glaucoma filtering surgery," International Ophthalmology, 20:89-94 (1997).	
	KG	Tanji, et al., "Fascia Lata patch Graft in Glaucoma Tube Surgery," Ophthalmology, 103:1309-1312 (1996).	
	KH	Tawakol, et al., "Gore-Tex Soft Tissue Bands as Scleral Explants in Rabbits: A Preliminary Histologic Study," Ophthalmic Surgery, 20:199-201 (1989).	
	KI	Watzke, "Scleral Patch Graft for Exposed Episcleral Implants," Arch Ophthalmol, 102:114-115 (1984).	
	KJ	Wilson, et al., "New hope for presbyopia: PMMA scleral bands show promise," Eyeworld, (1999); <a href="http://www.eyeworld.org/apr98/963.html">http://www.eyeworld.org/apr98/963.html</a>	

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WZ	LA	Wilson, et al., "Aqueous Shunts - Molteni versus Schocket," Ophthalmology, 99:672-678 (1992).	
	LB	Wilson-Holt, et al., "Hypertrophy flowing insertion of inferiorly sited double-plate Molteno tubes," Eye, (Pt. 5): 515-20 (1992).	
	LC	Yoshizumi, "Exposure of Intrasccleral Implants," Ophthalmology, 87:1150-1154 (1980).	
	LD	Yoshizumi, "Erosion of Implants in Retinal Detachment Surgery," Annals of Ophthalmology, 87:430-434 (1983).	
	LE	Banuelos et al., "Expandable Silicone Implants for Scleral Buckling," Arch Ophthalmol, 89:500-502 (1973).	

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